

IN THE U.S. PATENT AND TRADEMARK OFFICE

In re application of

Paolo MORAZZONI et al.

Conf. 5191

Application No. 10/587,468

Group 1655

Filed November 27, 2006

Examiner Qiuwen Mi

USE OF A GINKGO COMPLEXES FOR THE ENHANCEMENT OF COGNITIVE
FUNCTIONS AND THE ALLEVIATION OF MENTAL FATIGUE

DECLARATION UNDER RULE 132

Assistant Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Ezio BOMBARDELLI, hereby declare as follows:

I am a citizen of Italy and reside at Via Val di Sole,
22, Milano, Italy 20141. I obtained a degree in Biological
Science from the University of Pavia in 1962. From 1962 to 1989 I
was a researcher, and then Head of the Research Laboratory, at
the company "Inverni della Beffa S.p.A." - Milan. Since 1986 I
have been Scientific Director of INDENA S.p.A., Milano.

I am the author of more than 80 scientific
publications, most of which concern medicinal plant derivatives.
I am author and co-author of more than 30 patents, all concerning
medicinal plant derivatives. I am a member of the Italian
Chemical Society, Fédération Internationale Pharmaceutique

(F.I.P.), Gesellschaft für Arzneipflanzenforschung and Phytochemical Society of Europe.

I am familiar with the above-identified U.S. patent application and the applied references of SUMMERS (U.S. Patent 6,733,797 B1) and LOEW (Value of Ginkgo biloba in treatment of Alzheimer dementia, Wiener medizinische Wochenschrift (1946), (2002) Vol. 152, No. 15-16, pp. 418-22, Ref:40). The Office Action does not appear to have an appreciation for the fact that *Ginkgo biloba* extract complexed with phosphatidylserine can be used to enhance cognitive function and alleviate mental fatigue significantly above the levels provided by non-complexed extract.

To show that *Ginkgo*-phosphatidylserine complexes provide a remarkably higher and statistically significant activity over non-complexed compounds for the enhancement of cognitive function and alleviation of mental fatigue, I have performed Speed of Memory, Quality of Memory, and Picture Recognition Accuracy evaluations. These tests were carried out on 15 subjects of both sexes, and of age between 20 and 30 years. Each subject was treated with capsules respectively containing:

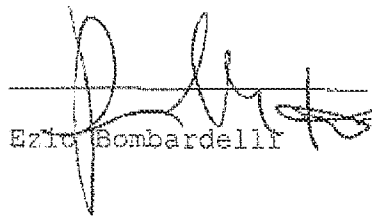
Ginkgo biloba extract (GE)	60 mg
Phospholipids containing 20%	
phosphatidylserine (PS)	180 mg
Mechanical mixtures containing GE and PS	240 mg
GE-PS complexes	240 mg

The Speed of Memory, Quality of Memory, and Picture Recognition Accuracy were evaluated as disclosed in the specification of US Patent Application 10/587,468. The results obtained show that capsules containing *Ginkgo biloba*-phosphatidylserine complexes show a remarkably and unexpectedly higher, and statistically significant, activity compared to capsules filled with *Ginkgo biloba* extract (GE), phosphatidylserine (PS), or mixtures of *Ginkgo biloba* extract and phosphatidylserine (GE + PS). The results of the Speed of Memory evaluation are shown in the graph.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

05/27/2009

(date)


Ezio Bombardelli

SPEED OF MEMORY

